

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

**PLAINTIFFS' STEERING COMMITTEE'S RESPONSE TO OBJECTIONS OF
ST. THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC**

On June 17, 2013, the Plaintiffs' Steering Committee ("PSC") served a subpoena (the "Subpoena") upon St. Thomas Outpatient Neurosurgical Center, LLC ("STOPNC" or the "Subpoenaed Party"). On July 1, 2013, STOPNC, through counsel, filed an Objection to the Subpoena (Dkt. No. 219, the "STOPNC Objection"). The PSC now files this response to the STOPNC Objection.

INTRODUCTION

STOPNC was one of the largest, if not the largest, customer of the New England Compounding Clinic ("NECC"), and its patients suffered the ramifications of that fact. In light of STOPNC's considerable relationship with NECC it is surprising, and disappointing, that STOPNC has exhibited such intransigence in helping the PSC in the aftermath of this tragedy.

The STOPNC Objection provides no basis to quash or otherwise modify the Subpoena. The STOPNC Objection offers only technicalities, red herrings and vague, unsupported legal arguments for the relief requested, and fails to provide any evidence to support its unfounded allegations that the Subpoena imposes an undue burden.

STOPNC has exhibited bad faith in its utter refusal to work with the PSC in obtaining highly critical documents to this litigation. It failed to attach the letter sent by the PSC in the meet and confer process, which directly addressed many of the arguments set forth in the STOPNC Objection.

In light of the considerable lack of any substance to the STOPNC Objection, it is clear what STOPNC's goal here is: Delay. Tennessee, the state in which STOPNC practices, has a one year statute of limitations, a statutory bar that is quickly approaching, and STOPNC's strategy to unnecessarily delay these proceedings is likely aimed at trying to run out this clock and limit its liability for providing tainted, NECC methylprednisolone acetate ("MPA") to its patients. The Court should not permit these obstructionist tactics and should immediately require STOPNC to respond, in full, to the Subpoena.

Finally, STOPNC sets forth only the flimsiest basis for the Court to quash the Subpoena based on undue burden. STOPNC provides no evidence or even makes any claim that producing responsive documents to the Subpoena would work a considerable hardship for it. Instead, STOPNC seeks to quash the Subpoena merely because it uses the term "all" in its requests and because some of the documents may be accessible from other sources like the CDC, FDA, and the New England Compounding Clinic ("NECC"). These are absurd arguments and provide no grounds for the Court to quash or alter the Subpoena.

In short, the Court should overrule the STOPNC Objection and require STOPNC to immediately respond to the Subpoena. Otherwise, Tennessee victims of this tragedy may lose their right to be made whole.

I. The Failure To Provide Witness Fees Has Been Cured

The STOPNC Objection first seeks relief from the Subpoena for failure of the Subpoena to be accompanied by the required witness fee under Rule 45. This technical error was cured by letter to counsel submitted on June 28, 2013, a copy of which is attached to this response as Exhibit A.

Although technical failures in providing witness fees can be cured or waived by the Court, this Court need not do that now as there is no legitimate argument that STOPNC has not be provided its witness fees. *See Adams v. Dolgencorp, LLC*, Case No. 11-784, 2012 U.S. Dist. LEXIS 71066 (M.D. La. May 22, 2012) (“[W]hile a subpoena request without the witness fee is technically invalid, the defect can be cured.”) (citing *Meyer v. Foti*, 720 F.Supp. 1234, 1244 (E.D.La. 1989)). Despite this, STOPNC insisted that the PSC reserve the Subpoena with a second check attached. Out of an abundance of caution, and in light of STOPNC’s insistence on re-service, the PSC reserved the Subpoena on July 8 mooting this point in its entirety. STOPNC’s highly technical, form over substance approach, provides STOPNC no relief and only distracts from the important work that needs to be done to ensure that victims of this tragedy are made whole.

In fact, STOPNC’s utter insistence on these technicalities is highly misplaced in light of the technical failure of the STOPNC Objection to itself satisfy certain technicalities required by this Court. Local Rules 7.1(a)(2), 26.2(c) require that any discovery motion be filed with a certificate of good faith consultation, which was not filed with the STOPNC Objection. Moreover, Local Rule 37.1 requires all discovery motions to set forth specific facts about the discovery conference held by the parties prior to filing any discovery related motion. There can be no doubt that the STOPNC Objection is such a motion, yet the motion fails to set forth the required information, presumably because STOPNC’s counsel failed to participate in good faith,

despite the PSC's attempts to do so, to narrow the issues now before this Court. Furthermore, as of last week, the PSC was still meeting and conferring with STOPNC on various issues in the subpoena and as of today, the PSC sent additional materials for STOPNC to review as part of the meet and confer process.

For example, by letter on June 28, 2013, the PSC agreed to narrow the scope of the Subpoena to conform to certain requests made by STOPNC's counsel in its original meet and confer letter. *See* Exhibit A. Despite that offer, the STOPNC Objection contains an allegation that the PSC breached and violated the Court's limited discovery by requesting documents outside of the January 2011 and November 2012 timeframe, but the STOPNC Objection fails to tell the Court that the PSC agreed to such a limitation.¹

By failing to engage in a good faith meet and confer process, by failing to attach the required certificates, and by failing to include in its Motion the information required by Local Rule 37.1, the STOPNC Objection fails on technicalities alone. *Howe v. Town of N. Andover*, 784 F. Supp. 2d 24 (D. Mass. 2011) (J. Gorton) (granting motion to strike discovery motion, in part, for parties' failure to comply with the "mandatory provisions of Local Rule 37.1(a)"). It is utterly unreasonable for the STOPNC Objection to require the PSC to meet all technicalities and then turn around and fail to do so itself. The Court should end these mindless games and order STOPNC to comply with the Subpoena.

II. The Subpoena Does Not Breach The Court's Limitation On Discovery

As already discussed, STOPNC's next claim that the Subpoena went beyond the discovery permitted by the Court is utterly unfounded. As demonstrated in Exhibit A, the PSC

¹ As discussed in greater detail below this is not the only example of the STOPNC Objection insisting this Court quash or modify the Subpoena on grounds that the PSC agreed to in the meet and confer process.

agreed to limit the documents produced pursuant to the Subpoena to be in accordance with the Court's Qualified Protective Order. Specifically, the letter states the following:

As an initial matter, the PSC agrees to limit the scope of the STOPNC Subpoena to require production of HIPAA-protected information only from January 2011-November 2012.

See Exhibit A, page 4.

This argument is nothing more than further indication of STOPNC's bad faith that it would now seek to quash the Subpoena on a ground that the PSC already consented to.

Further, the PSC is simply mystified by STOPNC's allegation that the Subpoena "circumvented the Court's requirement that the protected health information be produced to a vendor." This is patently incorrect. As can be demonstrated by the cover letter sent along with the Subpoena, the PSC originally requested that any HIPAA protected information be produced in accordance with the Court's Qualified Protective Order.² Further, in the June 28 Meet and Confer Letter, counsel once again clarified that HIPAA protected information need not be produced at the deposition but should only be produced in accordance with the Court's Qualified Protective Order. This is yet another indication of STOPNC's bad faith in pursuing to quash or modify the Subpoena and yet another indication of how, had STOPNC followed the Local Rules, this issue could have been resolved without the Court intervening.

Finally, STOPNC once again misleadingly claims that the PSC failed to append the Qualified Protective Order to the Subpoena. STOPNC fails to tell the Court that the order had not been issued at the time the PSC served the original STOPNC Subpoena, and the cover letter that accompanied the Subpoena indicated that the PSC anticipated the order would be issued shortly and the PSC would provide a copy of that Order once it was issued; which it did, as it was attached to the June 28 Meet and Confer Letter. This is yet another example of STOPNC's

² A copy of this letter is attached as Exhibit A to the STOPNC Objection.

bad faith and its improper attempt to put form over substance to circumvent its responsibilities on mere technicalities.

III. The Subpoena Is Not Unduly Burdensome

Next, STOPNC incorrectly, and without providing any evidence in support, claims that the Subpoena imposes an undue burden.³ “The party seeking to quash a subpoena bears a heavy burden of proof.” *Irons v. Karceski*, 74 F.3d 1262, 1264 (D.C. Cir. 1995). “When a non-party claims that a subpoena is burdensome and oppressive, the non-party must support its claim by showing how production would be burdensome.” *In re Subpoena Duces Tecum to AOL, LLC*, 550 F. Supp. 2d 606, 612 (E.D. Va. 2008). Given this heightened standard, the fact that STOPNC provides no evidence demonstrating burden and the fact that STOPNC’s legal arguments are utterly unfounded, STOPNC has failed to carry its substantial burden of showing that the Subpoena is unduly burdensome.

A. STOPNC Should Be Considered A Party

STOPNC incorrectly claims that it should be afforded special protection under Rule 45 because it is a “non-party” to this proceeding. Given the nature of this MDL, the party/non-party label is nothing more than a distinction without a difference. Although no complaint has been filed against STOPNC currently in the MDL, STOPNC will soon be defending cases in this MDL because STOPNC was one of the largest, if not the largest, customer of NECC and it is identified on the Center for Disease Control website as receiving tainted MPA and is also listed on the FDA’s list of customers of NECC. It simply makes no sense, and would be a waste of judicial resources, to grant STOPNC’s objection on this basis only to have it be mooted once a case is filed against STOPNC.

³ STOPNC claims that the standard for undue burden used in the Middle District of Tennessee should be used to determine undue burden in this case. The PSC does not believe that it needs to address this issue as STOPNC’s claims of undue burden fail under any standard used in federal courts.

B. STOPNC Fails To Show The Subpoena Is An Undue Burden

STOPNC, without any support or evidence, claims that it would be unduly burdensome to reply to the Subpoena and provides a litany of excuses, but no actual facts, to support its claim of undue burden.

First, STOPNC simply has not stated how production would be burdensome. It has provided no affidavit detailing the time and expense they estimate it will take to comply with the requests. STOPNC simply makes bald, unsupported, and broad allegations that the Subpoena imposes an undue burden; and as a result, the Subpoenaed Party has failed to meet its burden to quash or otherwise modify the subpoena. *See AF Holdings LLC v. Does*, 286 F.R.D. 39 (D.D.C. 2012) (refusing to quash subpoena when party, despite filing five declarations in support of motion to quash, failed to demonstrate with specificity the administrative burden it would incur in having to comply with a subpoena).

Instead of demonstrating with evidence the undue burden imposed by the Subpoena as required by law, STOPNC puts forth a litany of broad, vague, and unfounded legal theories as the basis of its burden argument.

First, STOPNC suggests that merely because the requests are broad (because they request “all” documents), the Subpoena imposes an undue burden, but that is clearly not the law. *Federal Communications Com. v. Cohn*, 154 F. Supp. 899, 1957 U.S. Dist. LEXIS 3187 (D.N.Y., September 5, 1957) (“Broadness alone does not make a subpoena invalid. A [subpoena] may require the production of all documents relevant to an inquiry.”)

Next, STOPNC strangely claims that because it produced thousands of pages of discovery in state court litigation that it would be an undue burden to respond to this Subpoena. This argument clearly detracts from STOPNC’s claim of undue burden as it appears that

STOPNC has already produced documents responsive to the Subpoena in alternative litigation. This may be why STOPNC was unable to come forward with an affidavit as to why it would take considerable time for STOPNC to reply to the Subpoena: it apparently has already done the work.

Next STOPNC incorrectly claims that the Subpoena imposes an undue burden because some of the documents requested by the PSC are easily accessible from other sources (i.e. the FDA, CDC, and state department of health). This is a red herring at best.

This argument ignores the fact that much of the information possessed by these entities related to STOPNC was collected from STOPNC in the first instance, as the CDC and the FDA required clinics, like the one operated by STOPNC, produce this information as part of their investigation into the outbreak of meningitis and other infections caused by tainted NECC products. In other words, STOPNC could just as easily provide much of the information possessed by the CDC and the FDA because it already collected it and sent it to the CDC and FDA in the first place. Moreover, STOPNC provides no basis for why obtaining this information from the CDC or FDA is in any way more or less burdensome – after all, these agencies are non-parties to this lawsuit and, unlike STOPNC, are never going to be parties – than obtaining them from STOPNC itself. There is no federal rule that requires the PSC to obtain information from the least burdened entity and such a rule would be absurd and lead to unnecessary litigation over who is in the best position to provide what discovery. In any event, the Court granted the PSC permission to seek this information from the clinics themselves and STOPNC operates such a clinic. There are simply no grounds to quash or modify the Subpoena based on the fallacy that merely because the CDC or the FDA may have possession of responsive

documents that STOPNC should be relieved from producing them – especially when STOPNC is responsible for producing those documents to those entities in the first instance.

The other remaining arguments STOPNC alleges support its claim for undue burden are equally unavailing. The PSC is not involved in a fishing expedition for clients⁴; the witness fees have been paid (twice at this point); merely because a request asks for “all” documents, does not mean that STOPNC can produce no documents; and merely because the Subpoena uses a defined term instead of naming STOPNC specifically in the request is wholly immaterial (and it is patently absurd that STOPNC would submit that as a basis for anything let alone fully quashing the Subpoena).

In short, STOPNC’s unfounded, unsupported, and wholly immaterial claims of undue burden fail as a matter of law. The Court should require STOPNC to comply with the Subpoena.

IV. The PSC Did Not Seek Privileged Information

The PSC is also mystified by STOPNC’s unfounded accusation that the Subpoena seeks the production of privileged information. As is clear from the June 28 Meet and Confer Letter, the PSC simply stated that if STOPNC wished to assert privilege of an otherwise responsive document, obviously it could do so and should produce a privilege log so that the PSC could evaluate any such claim.⁵

V. The Subpoena Permits a Reasonable Period of Time To Comply and Even if STOPNC Needed More Time, the PSC Offered a Reasonable Extension

⁴ As the Court is well aware, part of the information sought in the Subpoena (patient names and contact information for example) is done in conjunction with the NECC Bankruptcy Creditors’ Committee, as that information is highly relevant to providing adequate notice in that proceeding. In fact, the need for this information is accelerated by the Trustee’s recent attempts to set a bar date as early as September.

⁵ This applies with equal force to any claim of privilege under Tennessee’s Patient Safety and Quality Improvement Act of 2011. As stated in the June 28 Meet and Confer Letter to STOPNC’s counsel, if STOPNC wishes to withhold otherwise responsive documents based on any ground of privilege provided in this statute, it should simply produce a privilege log detailing those documents withheld so the PSC can evaluate the privilege claim.

STOPNC's claim that it was not permitted a reasonable time to comply with the subpoena is not in accordance with Rule 45 and, in any event, is a red herring in light of the PSC's offer to extend the time to reply to the Subpoena.

The Subpoena, served on June 17, 2013, requested that STOPNC respond by July 8, 2013. This gave STOPNC approximately three weeks to respond to the Subpoena, and STOPNC claims, without citation to any support, that the three week period was insufficient to respond to the Subpoena. Presumably, STOPNC's failure to cite to any support for this time period is due to the wealth of case-law supporting that a three week time to respond to a subpoena is sufficient under Rule 45. *See e.g., Lowe v. Vadlamudi*, Case No. 08-10269, 2012 U.S. Dist. LEXIS 127586 (E.D. Mich. Sept. 7, 2012) ("The text of Rule 45 does not support this argument, and the Court finds that twenty-one days is a reasonable time to comply."); *Linke Enterprises of Oregon, Inc. v. Champion Lab. Inc.*, Case No. 90-544, 1991 U.S. Dist. LEXIS 7155 (D. Ore. May 20, 1991) (holding that party is entitled to a reasonable time to comply under Rule 45 and permitting 21 days for compliance); *see also Thomas v. Rockin D Marine Servs., LLC*, Case No. 12-1315, 2013 U.S. Dist. LEXIS 60007 (E.D. La. April 25, 2013) (fourteen days is reasonable time to comply with subpoena); *Mann v. Univ. of Cincinnati*, 114 F.3d 1188 (Table), Nos. 95-3195, 95-3292, [published in full-text format at 1997 U.S. App. LEXIS 12482], (6th Cir. May 27, 1997) (approving magistrate judge's finding that fourteen days' notice is reasonable).

In any event the entire argument on timeliness is a red herring in light of the PSC's offer to extend the time for compliance if the party needed additional time. Specifically, Counsel offered the following in the meet and confer process:

To the extent that you may require additional time to produce responsive documents, we would consider a reasonable extension on this requirement, so long as you agree to produce responsive documents no later than July 22, 2013.

See Exhibit A, page 5.

Instead of working with the PSC to obtain a reasonable extension, STOPNC rushed to file its objections in a desperate and unfounded attempt to avoid ANY compliance with the Subpoena. This was not done in good faith and is certainly not grounds to quash, either in part or in whole, the Subpoena.

VI. The Subpoena Seeks Relevant Information and Does Not Impose an Undue Burden

As already discussed, the Subpoena does not impose an undue burden, but STOPNC once again makes another run at a claim that it did. STOPNC makes another unsupported allegation that the Subpoena seeks irrelevant information and is therefore unduly burdensome. “[R]elevancy is broadly construed at the discovery stage of litigation and a request for discovery should be considered relevant if there is any possibility that the information sought may be relevant to the subject matter of the action.” *Gagne v. Reddy*, 104 F.R.D. 454, 456 (D. Mass. 1984); *see also In re Texas Bumper Exchange, Inc. v. Veliz*, 333 B.R. 135 (2005) (“A party resisting discovery is swimming against a strong upstream policy current [where] the policy underlying the discovery rules encourages more rather than less discovery, and discourages obstructionist tactics.”)

STOPNC’s claims that its insurance policies, documents related to its corporate structure, and documents related to physicians that prescribed NECC products is irrelevant to claims pending in the MDL. Each of these assertions are simply absurd.

The Court specifically permitted the PSC to subpoena any information it “reasonably determines necessary to the prosecution and resolution of these actions.” (Dkt. No. 192 at ¶ 2.) Insurance policies of clinics and doctors that may have liability as a result of prescribing and

injecting tainted NECC pharmaceuticals into unsuspecting patients falls squarely within this information as it will enable the PSC, and possibly the Creditors' Committee, to assess the reasonableness of any settlement proposals; and will help ensure that any insurance proceeds are not unnecessarily exhausted in litigation costs and such proceeds can be passed onto the victims of this tragedy. Moreover, it is absolutely absurd to claim that insurance policies are irrelevant when the Federal Rules specifically require this information to be produced as part of initial disclosures. Fed. R. Civ. P. 26(a)(1)(iv). The very fact that the STOPNC Objection would take such a position is nothing more than further evidence of the unreasonableness in their objections and their continued bad faith in attempting to avoid their obligations under the Subpoena.

With regard to documents related to the corporate structure of STOPNC's practice (including bylaws, identity of officers and directors, and individuals with an ownership interest in its practice), this information is clearly relevant to the claims made in this proceeding as it will help the PSC identify any parties that may be liable for injuries suffered by victims, and will allow the PSC to identify potential witnesses that will help the PSC identify how and why STOPNC came to be a customer of NECC.⁶ Further, many of the pain clinics at issue in this litigation often change ownership structure on an ongoing basis, and the PSC should be entitled to investigate ownership interests and the identity of directors and officers to ensure that when suits are brought the correct entities are named.

STOPNC's practice is an excellent example of just this. Based on the PSC's preliminary investigation into STOPNC, STOPNC appears to be a joint venture between Howell Allen Clinic and a large hospital network known throughout Middle Tennessee, the Saint Thomas Hospital

⁶ This is particularly important in states like Tennessee, which have highly technical requirements on bringing claims sounding in medical malpractice and where failure to give pre-suit notice to all entities named in a lawsuit could be fatal to a given plaintiff's claims. *See e.g.*, T.C.A. § 29-26-121 (requiring that all healthcare facilities named in a lawsuit be given notice of a claim 60 days prior to filing a complaint).

Network. Moreover, many of the employees purportedly performing work for STOPNC are in fact Howell Allen Clinic employees, and the PSC has reason to believe that various persons and entities within the Saint Thomas Hospital Network play significant roles in the operations of STOPNC. It is simply absurd for STOPNC to claim that information related to its organization and structure is not “reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26.

This argument applies with equal, if not more, force to STOPNC’s claims that its communications with Howell Allen Clinic and the St. Thomas Hospital Network entities that mention NECC are not relevant to claims in the MDL. Most likely, STOPNC is simply concerned about the information the PSC will likely uncover when it is required to produce information related to how STOPNC interacts with its sister corporations, and STOPNC is trying one last Hail Mary to keep this information from being produced. The Court should not allow it to succeed.

Finally, with regard to the identity of physicians that prescribed NECC products, given the nature of the pain clinics at issue in this litigation, and the fact that many of them are staffed by a revolving cast of physicians, especially in rural areas, it is simply absurd for STOPNC to assert that the PSC should not be given a list of names of all physicians that practiced with STOPNC and prescribed NECC products.

Accordingly there is simply no basis in law or fact to quash or modify the Subpoena based on STOPNC’s unfounded assertions that the Subpoena seeks irrelevant information. *See Bariteau v. Krane*, 206 FRD 129 (W.D. Ky. 2001) (holding that if documents sought by subpoena duces tecum are relevant and are sought for good cause, then subpoena should be

enforced unless documents are privileged or subpoena is unreasonable, oppressive, annoying, or embarrassing.)

CONCLUSION

For the foregoing reasons, the STOPNC Objection should be overruled in its entirety, the Subpoena should not be quashed or modified, and the Court should order STOPNC to comply with the Subpoena.

Dated: July 15, 2013

/s/ J. Gerard Stranch, IV

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CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: July 15, 2013

/s/ J. Gerard Stranch, IV
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